K040162

MAR 16 2004

Section 2 — 510(k) Summary

Trade Name: CorRestore™ Patch System, new accessory

Common Name: Intracardiac Patch or Pledget

Establishment Information:
Somanetics Corporation
1653 East Maple Road
Troy, MI 48083
Phone: (248) 689-3050
Fax: (248) 689-4272

Contact Person: Ronald A. Widman, Vice President of Medical Affairs

Classification: Class II, Panel 74 DXZ

Product Description:
The CorRestore Patch is an oval tissue patch made from glutaraldehyde fixed bovine pericardium. It is intended to be used as an intracardiac patch for cardiac reconstruction and repair. It is identical to other marketed bovine pericardium patches except that it incorporates an integral suture bolster (also made of fixed bovine pericardium) in the shape of an oval ring and is packaged with accessories needed for cardiac repair and reconstruction. The CorRestore Patch comes as a kit including a patch and suture strip (1.4 x 16 cm), both manufactured from processed bovine pericardium. Optionally included is a set of various sutures needed for implantation. To assist the surgeon in determining the appropriate size, a separate disposable sizer kit is offered. A silicone balloon (CRB) is optional to allow the surgeon to check left ventricular diastolic volume prior to closure.

The CorRestore Patch comes in three sizes:

Without Sutures	W/ Ethicon Sutures	W/ Genzyme Sutures	Product
1.5P2	1.5P2S	1.5P2SG	1.5 x 2 cm* CorRestore Patch
2P3	2P3S	2P3SG	2 x 3 cm* CorRestore Patch
3P4	3P4S	3P4SG	3 x 4 cm* CorRestore Patch

*Sizes refer to inside dimensions of suture ring; actual sizes are larger

Accessories:

CRPS	CorRestore Patch Sizer Set
CRB	CorRestore Balloon

Substantial Equivalence:
The CorRestore patch is substantially equivalent to the predicate Chase Medical Cardiovascular Patch Kit, K022093.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2004

Somanetics Corporation
c/o Mr. Ronald A. Widman
Vice President of Medical Affairs
1653 East Maple Road
Troy, MI 48083

Re: K040162
CorRestore™ Patch System
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac Patch or Pledget
Regulatory Class: Class II (two)
Product Code: DXZ
Dated: January 23, 2004
Received: January 26, 2004

Dear Mr. Widman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040162

Device Name: CorRestore™ Patch System Processed Bovine Pericardial Patch

Indications For Use: The CorRestore patch is intended for cardiac reconstruction and repair.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040162